

REMARKS

A. Status of the claims

Claims 1, 2 and 8 have been amended, claims 5-6 and 13-16 are canceled and new claim 18 has been added. Thus, claims 1-4, 7-12 and 17-18 are currently pending and under examination. Support for the amendment to claim 1 can be found in original claims 2 and 6. The amendment to claim 8 is supported by text at page 15, lines 6-8. Support for new claim 18 can be found through-out the specification and in particular in original claim 1. No new matter has been added.

B. Objections regarding the use of Trademarks

The Examiner objected to portions of the specification and to claim 8 as allegedly improperly citing trademarks. Applicants are not aware of any specific trademark concerning the red and green Alexa dyes recited in claim 8. Nonetheless, to further clarify the claim language Applicants have amended the claim to recite the Alexa-488 and Alexa-647 dyes (which are also not believed to be Trademarks). Support for the foregoing amendment can be found at least on page 15, lines 6-8 of the specification. Moreover, Applicants provide herewith an amendment to the specification which properly references trademarks that are recited therein (*e.g.*, TEXAS REDTM). The portion of text that has been amended refers to fluorescent dyes that are known in the art and thus Applicants have also provided the requisite generic terminology.

C. Priority claim

The Examiner has acknowledged the priority claim to Great Britain Application No. GB0308852.5 filed on April 16, 2003, but notes that a certified copy of the application has not be filed with the U.S. Patent & Trademark Office (U.S. PTO)). A certified copy of the priority document was, however, filed with the International Bureau of the World Intellectual Property Organization (WIPO) and the certified copy should have been forward to the U.S. PTO upon national filing of the application. As evidence of that the priority document was submitted, Applicants enclose herewith a copy of a Notification from the International Bureau of WIPO that indicates the priority document was received on May

18, 2004. Thus, a copy of the priority application should be available to the U.S. PTO by requesting a copy from WIPO.

D. Rejections under 35 U.S.C. §112, first paragraph are moot

The Examiner rejected claims 1-5, 7-12 and 17 as allegedly lacking enablement under 35 U.S.C. §112, first paragraph. In particular the Examiner indicates that while written description in the specification is sufficient to enable a skilled worker to identify a series of characteristics such a sequences of a polynucleotide molecule, it does not enable methods for identifying characteristics on any molecule. However, the claims have been amended to define the characteristics identified by the method as partial or complete sequence of a target polynucleotide. This aspect was originally recited in claim 6, which was not subject to the instant enablement rejection. Thus, the rejection under 35 U.S.C. §112, first paragraph is moot and its withdrawal is requested. Applicants reserve the right to pursue claims to the original subject matter in continuing applications.

E. Rejections under 35 U.S.C. §112, second paragraph are overcome

The Examiner rejected claims 1-5, 7-12 and 17 as allegedly indefinite under 35 U.S.C. §112, second paragraph. For instance the Examiner alleges that the specification is unclear as to the meaning of the phrase “characteristics of a molecule.” Claim 1 has been amended herein to define the characteristics identified by the method as “partial or complete sequence of the target polynucleotide,” rendering moot the basis for rejection. This aspect was originally recited in claim 6—a claim not subject to the intent rejection.

The Examiner rejected claim 4 (and dependent claim 17) as indefinite as to the meaning of the term “targets.” However, claim 1, as amended, provides proper antecedent basis for the term “targets.” For example step (i) of claim 1 indicates that “each unit on a polynucleotide comprises two or three of the different bases A, T(U), G and C, one of which represents a target for subsequent incorporation for incorporation of a detectably labeled nucleotide.” Thus, the term “targets” as used in the claim 4 (i.e., targets for the incorporation of labeled nucleotides) refers to the nucleotide base which is part of a unit in a polynucleotide, a meaning which is defined in claims 1. Furthermore, the terms “same type”

(claim 4) and “different type” (claim 17) refer to the (nucleotide) bases in a unit of a polynucleotide. Even if it were not clear to the skilled worker what the meaning of the terms “same” and “different” bases was from the knowledge in the art, claim 1 unambiguously defines the different bases in step (i) as A, T(U), G and C.

Thus, in view of the foregoing the rejection of claims 1-5, 7-12 and 17 as allegedly indefinite under 35 U.S.C. §112, second paragraph has been overcome, and its withdrawal is requested.

F. Rejections under 35 U.S.C. §102(b), are overcome

Claims 1, 3, 5-7 and 9-11 have been rejected as allegedly anticipated under 35 U.S.C. §102(b) by Rosenthal et al. (WO 1993/21340). At the outset Applicants note that claim 2 was not subject to the instant rejection and aspects of claim 2 have now been incorporated into claim 1. In particular, claim 1 now defines that “each unit on the polynucleotide comprises two or three of the different bases A, T(U), G and C.” The disclosure of Rosenthal et al. does not teach or suggest methods for identifying characteristics (different units) of a polynucleotide wherein each unit comprises two or three (*i.e.*, more than one) of the different bases. Thus, Rosenthal et al. fails to disclose all elements recited in the instant claims. Accordingly, the rejection of claims 1, 3, 5-7 and 9-11 under 35 U.S.C. §102(b) has been overcome and its withdrawal is requested.

G. Rejections under 35 U.S.C. §103(a), are overcome

Claims 2, 4, 12 and 17 have been rejected as allegedly obvious under 35 U.S.C. 103(a) over Rosenthal et al. in view of Jones et al. (WO 2000/39333). However, none of the references cited alone or in combination teach a method as recited in claim 1 (or claim 18). For example, claims 1 and 18 states that “each unit on the polynucleotide comprises *two or three of the different bases* A, T(U), G and C, one of which represents *a target for the subsequent incorporation of a detectably labelled nucleotide*, and one which *represents a stop signal*.” (emphasis added) The Examiner has failed to identify any teaching that a unit should comprise more than one different base wherein one base represents a target for incorporation and another base represents a stop signal. The Examiner cites Figure 7 of Jones

et al. and states that the figure teaches a “a stop ‘G’ base;” however, as the Examiner indicted in the rejection the stop “G” base is incorporated to stop ligation not nucleotide incorporation. On the other hand, the instant claims refer to both a target base for incorporation and a stop signal to halt the incorporation. No such teaching has been identified in any reference cited in the rejection. In view of the foregoing no *prima facie* case for obviousness of the claims under 35 U.S.C. §103(a) has been set forth.

Moreover, the skilled worker would not be motivated to combine the teachings of Rosenthal et al. and Jones et al. because the two references concern very different techniques for sequencing. For example, the techniques of Jones et al. do incorporate a polymerase reaction as a required step. Furthermore, the disclosure of Rosenthal et al. explicitly teaches away from methods defined in the instant claimed. For example, Rosenthal teaches a polynucleotide sequencing method which comprises “c) extending the primer by the addition of a *single* labelled nucleotide,” (see, page 7, lines 11-12 of Rosenthal et al. (emphasis added)). Furthermore, beginning at page 10, line 8, Rosenthal et al. describes the problems associated with reactions that result in the addition of more than one base and discloses methods for *preventing* the inadvertent additional of more than a single nucleotide. Thus, the disclosure of Rosenthal et al. explicitly teaches away from a method wherein each unit that is characterized comprises more than a single nucleotide. Even if all elements of the instant claims were taught by the combination of Rosenthal et al. and Jones et al. a person of ordinary skilled would not have been motivated to combine the teachings Rosenthal et al. and Jones et al. especially in view of the disclosure of Rosenthal et al. which teaches away from the claimed methods. In view of the foregoing the instant rejection of claims 2, 4, 12 and 17 as obvious under 35 U.S.C. 103(a) has been overcome and its withdrawal is requested.


Claim 8 has been further rejected as allegedly obvious under 35 U.S.C. 103(a) over Rosenthal et al. in view of Rusinova et al. However, Rusinova et al. does not address the underlying deficiencies in rejection of claim 1 from which claim 8 depends. Thus, the rejection of claim 8 over Rosenthal and Rusinova et al. is considered moot in view of the amendments and arguments detailed above.

H. Conclusion

In view of the above amendment and argument, Applicants believes the pending application is in condition for allowance. The Examiner is invited to contact David Gass or the undersigned with any questions or concerns.

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Respectfully submitted,

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